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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,034	04/23/2001	Gerardo Castillo	PROTEO.P07CI3	4033

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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,034	CASTILLO ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-25* is/are rejected.

7)☒ Claim(s) *21,24,25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 20-25 are presented for examination.

Applicant's Amendment filed May 2, 2006 has been received and entered into the present application.

Claims 20-25 remain pending and are currently under examination. Claims 2, 3, 6, 8-11, 13, 16, 17 and 19 have been cancelled and no claims have been amended.

Regrettably, the allowability of the instant claims as noted in the previous Office Action dated November 30, 2005 is withdrawn in view of the new grounds of objection and rejection set forth below.

Objections to the Claims (New Grounds of Objection)

Claim 21 is objected to for failing to conclude with a period.

Claims 24 and 25 are objected to for depending upon cancelled claims 17 and 19, respectively. For the purposes of examination, present claim 24 will be interpreted as depending from claim 20 and present claim 25 will be interpreted as depending from claim 21.

Claim Rejections - 35 USC § 112, First Paragraph (New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of Type II diabetes and the inhibition, dissolution, reduction or disruption of amyloid fibrils in a subject using the claimed composition, does not reasonably provide enablement for the elimination or prevention of amyloid fibrils in a subject using the claimed

composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art;
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art.

The relevant factors are addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

The present rejection is also made under the guidance of the MPEP at §2164.01(c), which states, "When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that limitation. See *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991)." Thus, the instant rejection made under 35 U.S.C. 112, first paragraph, is proper as it is applied to the present composition claims 22-23 because the claims are drawn to a composition for the elimination or prevention of amyloid fibrils in a subject.

The present invention is directed to compositions comprising plant matter from a plant of the genus *Uncaria*, species *tomentosa* (i.e., cat's claw) in combination with various herbal compounds and vitamins for the reduction, disruption, dissolution, inhibition, elimination or prevention of amyloid fibrils in a subject. As disclosed in the specification, the amyloid fibrils are those that result from Alzheimer's disease (see pages 1-2 of the specification) and, thus, the claimed compositions circumscribe uses of the

composition for eliminating or preventing the development of amyloid fibrils resulting from Alzheimer's disease.

In particular, one skilled in the art could not practice the presently claimed subject matter of eliminating or preventing amyloid fibril formation by administering the claimed combination of active agents without undue experimentation because the artisan would not accept on its face that the elimination or prevention of amyloid fibrils could actually be achieved given the state of the art at the time of the invention. Based upon the state of the art, as discussed below, and the evidence presented by Applicant, the artisan would have only accepted that the amyloid fibrils could be inhibited, dissolved, reduced or disrupted in a subject with such a composition.

As set forth in *In re Marzocchi et al.*, 169 USPQ 367 (CCPA 1971):

"[A] [s]pecification disclosure which contains the teachings of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with the enabling requirement of first paragraph of 35 U.S.C. 112, *unless there is reason to doubt the objective truth of statements contained therein which must be relied on for enabling support;* assuming that sufficient reasons for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in the specification is truly enabling." (emphasis added)

The present claims circumscribe the use and administration of the presently claimed combination of agents for the elimination and prevention of amyloid fibrils, such as those that result from the development of Alzheimer's disease, in a subject in need thereof. That is, in order to be enabled to practice the present invention, the skilled artisan would have to accept that by administering a pharmaceutical composition comprising plant matter from *Uncaria tomentosa* in combination with various herbal compounds and/or vitamins that any amyloid fibrils that had already developed would be

eradicated (i.e., eliminated) or that amyloid fibrils would actually be prevented from developing or worsening. In other words, the skilled artisan would have understood the terms "elimination" or "prevention", in their broadest reasonable interpretation consistent with MPEP §2111, to mean that the incidence or progression of amyloid fibrils after administration of the presently claimed combination of agents would essentially be 0% and could be reasonably expected not to develop, occur or recur. In light of the fact that the specification fails to provide the skilled artisan with any direction or guidance as to how the elimination or prevention of amyloid fibrils could actually be achieved, since the disclosure is solely directed to the concept of reduction, disruption, dissolution or inhibition of amyloid fibrils in patients that already exhibit such fibrils, the present specification is viewed as lacking an enabling disclosure of the entire scope of the claimed invention.

Regarding the elimination or prevention of amyloid fibrils as they are associated with Alzheimer's disease, the objective truth that the development of such a condition could be prevented from occurring or that amyloid fibrils could be eliminated is doubted because, while the state of the art with regard to the reduction or disruption of amyloid fibrils associated with Alzheimer's disease may be achieved, the state of the art with regard to the definitive elimination or prevention of such fibrils (in essence, the elimination or prevention of Alzheimer's disease) is grossly underdeveloped.

The objective truth of the statement that the amyloid fibrils associated with Alzheimer's disease may be eliminated or prevented is doubted because the disease itself is particularly elusive and manifests itself in a variety of different ways in different subjects such that the diagnostician cannot be sure that the disease is truly the cause of the signs and symptoms of disorder exhibited by the patient. A diagnosis of Alzheimer's disease is tentative, at best, until confirmation of the diagnosis can be confirmed by the presence of amyloid deposits in the brain at autopsy (see Cecil's Textbook of Medicine, "Differential Diagnosis", page 2043 at column 1).

Such difficulties in diagnosis are recognized in the art. Applicant's attention is drawn to Cecil's

Textbook of Medicine, which states, "In a patient with clinical findings suggesting Alzheimer's disease, other causes of dementia should be excluded by history, examination, and the laboratory studies described above. CSF evaluation for amyloid protein and tau protein can increase the likelihood of a diagnosis of Alzheimer's disease, but they are not sufficiently specific to be of routine value in screening or early diagnosis of Alzheimer's disease...Presence of the apoE4 allele makes it very likely that the patient's dementia is produced by Alzheimer's disease. ApoE testing does not have predictive value for asymptomatic individuals." (see Cecil's Textbook of Medicine, "Diagnosis", column 2 at page 2044)

In this regard, it is also noted that the art acknowledges only certain criteria for definitive diagnosis of Alzheimer's disease, see in particular Gauthier et al., (Can. Med. Assoc. J, Oct 15, 1997, 157(8): 1047-52), Greicius et al. (J Neurol. Neurosurg. Psychiatry, 2002 Jun; 72(6):691-700) and Gasparini et al. (FASEB J., 12, Jan. 1998, pp. 17-34). Post mortem analysis of brain tissue for the characteristics of amyloid plaques is considered necessary for a definitive diagnosis. This is because the art has come to recognize its presence in essentially all cases. However, to achieve diagnostic status took years of evaluative procedures, both pre- and post-mortem, confirming that every case had a degree of this pathology. Even so, diagnostic application is often problematic given variable peptide expression patterns among clinically similar and dissimilar diseases states (see Greicius et al.).

Given that there a only a few factors that are recognized to have moderate, if any, predictive value in determining the likelihood that patients develop such a disease or to even determine whether patients actually have such a disease, since many of the early signs of Alzheimer's disease are common complaints of aging or result from other neurological conditions, such as depression, where memory impairment is not present (see Cecil's Textbook of Medicine, "Evaluation of Dementia", column 1, page 2042), one of ordinary skill in the art would not accept on its face Applicant's statement that the amyloid fibrils directly resulting from Alzheimer's disease could be prevented or eliminated using the presently claimed active agents. In fact, such complexity of diagnosis precludes a common, art-accepted protocol

for preventing Alzheimer's disease in any patients, given that the circumstances or risk factors are unique to that individual and must be considered on a case-by-case basis when determining the most effective approach to preventing Alzheimer's disease.

In other words, not only is the population in need of such treatment not well defined in the art because of the difficulties associated with making an accurate diagnosis, but the disease is also sufficiently complicated and poorly understood such that the idea that any active agent (including that presently claimed) would be capable of preventing or eliminating such a condition via administration of the presently claimed agent(s) would not have been reasonably expected by the skilled artisan. The artisan would have required sufficient direction as to how the administration of the presently claimed active agent(s) could actually determine the population of patients in need of prevention and how the presently claimed agent(s) could actually eliminate Alzheimer's disease such that the artisan would have been imbued with at least a reasonable expectation of success. Such success would not have been reasonably expected given that the concept of a single agent, or even a combination of agents, that is effective against the development of Alzheimer's disease or that is effective in eradicating such a disease from a host would have been unique and, thus, met with a great deal of skepticism.

It is in this regard that Applicant is directed to the MPEP at §2164.08. All questions of enablement are evaluated against the claimed subject matter. Concerning the breadth of a claim relevant to enablement, the only relevant concern is whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. The determination of the propriety of a rejection based upon the scope of a claim relative to the scope of enablement involved the determination of how broad the claim is with respect to the disclosure and the determination of whether one skilled in the art is enabled to use the *entire scope* of the claimed invention without undue experimentation.

Applicant provides various studies in the specification directed to the use of the claimed

compositions. Study 1 assesses the effects of a claimed combination on amyloid fibril formation associated with Alzheimer's disease. Study 2 assesses the effects of a claimed combination on amyloid fibril growth associated with Alzheimer's disease. Study 3 assesses the effects of a claimed combination on amyloid beta-glycosaminoglycan interactions associated with Alzheimer's disease. Study 4 assesses dose-dependent effects on causing dissolution or disruption of pre-formed amyloid (1-40) fibrils associated with Alzheimer's disease. Study 5 assesses the dose dependent effects on causing dissolution or disruption of pre-formed amyloid 1-42 fibrils associated with Alzheimer's disease. Please see pages 10-15 of the specification.

Results of these studies demonstrate that a claimed combination, i.e., PTI-00703 and Gingko biloba was a potent inhibitor of amyloid fibril formation (study 1), was effective in inhibiting amyloid fibril growth (study 2), was an inhibitor of beta-amyloid protein-PG/GAG interactions (study 3), was effective in causing dissolution or disruption of pre-formed amyloid (1-40) fibrils in a dose-dependent manner (study 4) and was effective in causing dissolution or disruption of pre-formed amyloid (1-42) fibrils in a dose-dependent manner (study 5). Please see pages 15-17 of the specification.

However, none of these studies demonstrates the ability of the claimed composition to effectively eliminate or prevent the formation or worsening of amyloid fibrils associated with Alzheimer's disease. While a lack of a working embodiment cannot be the sole factor in determining enablement, the absence of substantial evidence commensurate in scope with the presently claimed subject matter, in light of the unpredictable nature of the art and the direction that Applicant has presented, provides additional weight to the present conclusion of insufficient enablement in consideration of the *Wands* factors as a whole. The instant specification conspicuously lacks any disclosure or teaching of manner and process of using the presently claimed composition for achieving the objective of preventing or eliminating amyloid fibrils associated with Alzheimer's disease. Nowhere does the specification disclose how those patients at risk for developing such fibrils could be identified, what criteria would be used to determine such patients and

how they would be treated using the presently claimed composition such that the skilled artisan would have been imbued with at least a reasonable expectation of success in determining the patient population in need of prevention or elimination of amyloid fibrils without the burden of an undue level of experimentation.

In view of the discussion of each of the preceding seven factors, the level of skill in the art is high and is at least that of a medical doctor with several years of experience in the art.

As the cited art and discussion of the above factors establish, practicing the claimed method in the manner disclosed by Applicant would not imbue the skilled artisan with a reasonable expectation that ht elimination or prevention of amyloid fibrils associated with Alzheimer's disease could be achieved. In order to actually achieve such a result, it is clear from the discussion above that the skilled artisan could not rely upon Applicant's disclosure as required by 35 U.S.C. 112, first paragraph, and would have no alternative recourse but the impermissible burden of undue experimentation in order to practice the full scope of the presently claimed invention.

Claim Rejections - 35 USC § 102 (New Grounds of Rejection)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 21, 23 and 25 are rejected under 35 U.S.C. 102(a) as being anticipated by Womack et al. (U.S. Patent No. 5,730,988; March 1998).

Womack et al. teaches nutritional supplements that improve glucose metabolism, which comprise a "Phase I supplement", comprising chromium picolinate, niacinamide, vitamin B1, huckleberry and ginseng, and a "Phase II supplement", comprising cat's claw, folic acid, selenium, vitamin B1 and niacinamide, wherein the first (i.e., Phase I supplement) and the second (i.e., Phase II supplement) nutritional supplements can be combined into a single pill, and further wherein the supplement may contain other vitamin or minerals. Please see the abstract, column 6, lines 42-65, and Example 1, column 8, line 21-62.

Though Womack does not explicitly teach the administration of the disclosed composition for the reduction, disruption, dissolution, inhibition, elimination or prevention of amyloid fibrils (see present claim 23), such a limitation is an intended use of the composition and fails to impart any physical or material characteristic to the composition that would not already be present in the prior art composition of Hastings et al.

Additionally, in light of the fact that Womack teaches a pharmaceutical composition of identical components to that presently claimed, the amyloid inhibitory activity or efficacy that Applicant presently claimed is inherently present in the composition disclosed by Womack. As taught by the MPEP, products of identical composition cannot have mutually exclusive properties. Please reference MPEP §2112.01.

Claims 20, 22 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Hastings et al. (U.S. Patent No. 6,224,871; Issued 2001, Filed March 1998).

Hastings et al. teaches dietary compositions for promoting healthy joint function comprising gingko biloba, cat's claw powder (*Uncaria tomentosa*), echninacea root, bilberry extract, and aloe vera extract, which may be administered to a subject orally. Please reference column 1, line 61-column 2, line 18; column 4, lines 50-58; and column 5, lines 35-41.

Though Hastings et al. does not explicitly teach the administration of the disclosed composition for the reduction, disruption, dissolution, inhibition, elimination or prevention of amyloid fibrils (see

present claim 22), such a limitation is an intended use of the composition and fails to impart any physical or material characteristic to the composition that would not already be present in the prior art composition of Hastings et al.

Additionally, in light of the fact that Hastings et al. teaches a pharmaceutical composition of identical components to that presently claimed, the amyloid inhibitory activity or efficacy that Applicant presently claimed is inherently present in the composition disclosed by Hastings et al. As taught by the MPEP, products of identical composition cannot have mutually exclusive properties. Please reference MPEP §2112.01.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Applicant's declaration executed under 37 C.F.R. 1.131(b) to overcome the previous application of Hastings et al. as prior art has been noted, but is insufficient. In particular, Applicant has failed to establish that conception of the presently claimed invention occurred prior to the effective date of the Hastings et al. reference (March 11, 1998). It appears from Applicant's declaration that conception of the claimed invention occurred after the 102(e) filing date of the Hastings et al. reference. The statements in paragraph (4), which pertain to the inventive compositions of the instant application, appear to indicate that conception occurred sometime between May 15, 1998 and August 30, 1998, which is after the effective filing date of Hastings et al. Moreover, the declaration does not establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Hastings et al. patent. Accordingly, constructive reduction to practice for the instant invention appears to

have been when the provisional application was filed (August 30, 1998), which is after the filing date of Hastings et al.

As stated in 37 C.F.R. 1.131(b), "The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application. Original exhibits of drawings or records, or photocopies thereof, must accompany and form part of the affidavit or declaration or their absence must be satisfactorily explained." Applicant has failed to provide any original exhibits or evidence in support of their assertion that conception of the presently claimed invention occurred prior to the filing date of Hastings et al. While the absence of evidence in the record is not, in and of itself, grounds to dismiss a claim that conception occurred prior to a cited reference, Applicant has failed to provide any explanation as to why such evidence was not otherwise presented to the Office.

Claim Rejections - 35 USC § 103 (New Ground of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner

to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Womack (U.S. Patent No. 5,730,988; March 1998) in view of Hsia et al. (U.S. Patent No. 5,976,548; Issued 1999, Filed 1997).

Womack et al. teaches nutritional supplements that improve glucose metabolism, which comprise a "Phase I supplement", comprising chromium picolinate, niacinamide, vitamin B1, huckleberry and ginseng, and a "Phase II supplement", comprising cat's claw, folic acid, selenium, vitamin B1 and niacinamide, wherein the first (i.e., Phase I supplement) and the second (i.e., Phase II supplement) nutritional supplements are combined into a single pill, and further wherein the supplement may contain other vitamin or minerals. Please see the abstract, column 6, lines 42-65, and Example 1, column 8, line 21-62.

Hsia et al. teaches nutritional supplements for the human diet for decreasing serum glucose in human plasma (see abstract) and also, for example, strengthening connective and structural tissues (see column 2, line 66-column 3, line 5). Hsia et al. teaches nutritional supplements comprising chromium, selenium, niacinamide, folate, vitamin B12 and choline (see Example 1, Table bridging columns 13-14).

One of ordinary skill in the art would have been motivated to combine the composition of Womack with the composition of Hsia et al. because each composition was known in the prior art to have the same serum glucose reducing effects. The very fact that each was known in the art to have the same therapeutic utility raises the reasonable expectation of success that the two compositions, when combined, would have, at minimum, additive, if not synergistic, serum glucose reducing effects when combined.

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980): "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In*

re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960)."

Claims 20, 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings et al. (U.S. Patent No. 6,224,871; Issued 2001, Filed March 1998) in view of Hsia et al. (U.S. Patent No. 5,976,548; Issued 1999, Filed 1997).

Hastings et al. teaches dietary compositions for promoting healthy joint function comprising gingko biloba, cat's claw powder (*Uncaria tomentosa*), echinacea root, bilberry extract, and aloe vera extract, which may be administered to a subject orally. Please reference column 1, line 61-column 2, line 18; column 4, lines 50-58; and column 5, lines 35-41.

Hsia et al. teaches nutritional supplements for the human diet for, e.g., strengthening connective and structural tissues (see column 2, line 66-column 3, line 5). Hsia et al. teaches nutritional supplements comprising ginseng, vitamin E, selenium, niacinamide, folate, vitamin B12 and choline (see Example 1, Table bridging columns 13-14).

One of ordinary skill in the art would have been motivated to combine the composition of Hastings et al. with the composition of Hsia et al. because the composition of Hastings et al. was known to promote healthy joint function and the composition of Hsia et al. was known to strengthen connective and structural tissues, tissues which are known to be integral components of human joints. In other words, each composition was known in the prior art to have joint heath enhancing effects. The very fact that each was known in the art to have the same therapeutic utility raises the reasonable expectation of success that the two compositions, when combined, would have, at minimum, additive, if not synergistic, joint health promoting effects when combined.

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980): "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for

the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960)."

Conclusion

Rejection of claims 20-25 is deemed proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

September 27, 2006

Ardin H. Marschel 9/29/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER